

## Westlaw.

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Fellner v. Tri-Union Seafoods, L.L.C.  
C.A.3 (N.J.),2008.

Only the Westlaw citation is currently available.

United States Court of Appeals,Third Circuit.  
Deborah FELLNER, individually and on behalf of  
those similarly situated  
v.

TRI-UNION SEAFOODS, L.L.C. d/b/a Chicken of  
the Sea Deborah Fellner, Appellant.  
**No. 07-1238.**

Argued Feb. 12, 2008.

Opinion Filed: Aug. 19, 2008.

**Background:** Consumer diagnosed with mercury poisoning sued manufacturer of tuna products in state court, seeking, inter alia, damages under New Jersey Products Liability Act (NJPLA) based on manufacturer's failure to warn of risks of consuming its products. After action was removed, the United States District Court for the District of New Jersey, Dennis M. Cavanaugh, J., 2007 WL 87633, granted manufacturer's motion to dismiss on federal preemption grounds. Consumer appealed.

**Holdings:** The Court of Appeals, Stapleton, Circuit Judge, held that:

- (1) advisory published by Food and Drug Administration (FDA) and related "backgrounder" were not entitled to court deference in deciding whether consumer's claims were preempted;
- (2) FDA letter opining about preemptive effect of its prior actions was not persuasive;
- (3) FDA had not adopted regulatory scheme that could preempt consumer's action;
- (4) actual conflict required for preemption did not exist based on FDA's purported decision not to regulate; and
- (5) no actual conflict existed between claims and FDA's misbranding regulatory authority under Food, Drug and Cosmetics Act (FDCA).

Reversed and remanded.

# [1] Federal Courts 170B 763.1

170B Federal Courts

170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent

170BVIII(K)1 In General

170Bk763 Extent of Review Depend-  
ent on Nature of Decision Appealed from

170Bk763.1 k. In General. Most

Cited Cases

Court of Appeals exercises plenary review of dis-  
trict court order granting defendant's motion to dis-  
miss for failure to state claim. Fed.Rules  
Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

# [2] Federal Courts 170B 794

170B Federal Courts

170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent

170BVIII(K)3 Presumptions

170Bk794 k. Pleadings. Most Cited

Cases

When reviewing dismissal for failure to state claim,  
Court of Appeals accepts as true all well-pled factu-  
al allegations in the complaint and all reasonable  
inferences that can be drawn from them, and will  
affirm order of dismissal only if the pleading does  
not plausibly suggest an entitlement to relief.  
Fed.Rules Civ.Proc.Rule 12(b)(6), 28 U.S.C.A.

# [3] States 360 18.11

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.11 k. Congressional Intent. Most

Cited Cases

Inclusion of express preemption provisions in fed-  
eral legislation does not preclude the operation of  
ordinary implied preemption principles.

# [4] States 360 18.9

360 States

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## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

Although preemption fundamentally is a question of congressional intent, state laws can be preempted by federal regulations as well as by federal statutes. U.S.C.A. Const. Art. 6, cl. 2.

**[5] States 360 18.9**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

When Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency's delegated authority. U.S.C.A. Const. Art. 6, cl. 2.

**[6] States 360 18.3**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.3 k. Preemption in General. Most Cited Cases

It is federal law which preempts contrary state law; nothing short of federal law can have that effect. U.S.C.A. Const. Art. 6, cl. 2.

**[7] States 360 18.9**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

In appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal notice-and-comment rulemaking may have preemptive effect over state law. U.S.C.A.

Const. Art. 6, cl. 2.

**[8] States 360 18.9**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

Federal agency orders resulting from quasi-judicial agency proceedings may constitute federal law with preemptive effect under the Supremacy Clause. U.S.C.A. Const. Art. 6, cl. 2.

**[9] States 360 18.9**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

Federal law capable of preempting state law is not created every time someone acting on behalf of an agency makes a statement or takes an action within the agency's jurisdiction, and preemptive effect is not afforded to less formal agency measures lacking the fairness and deliberation which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law. U.S.C.A. Const. Art. 6, cl. 2.

**[10] States 360 18.9**

## 360 States

## 360I Political Status and Relations

## 360I(B) Federal Supremacy; Preemption

## 360k18.9 k. Federal Administrative Regulations. Most Cited Cases

Mere deliberate federal agency inaction, meaning an agency decision not to regulate an issue, will not alone preempt state law. U.S.C.A. Const. Art. 6, cl. 2.

**[11] States 360 18.5**

## 360 States

## 360I Political Status and Relations

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### 360I(B) Federal Supremacy; Preemption

360k18.5 k. Conflicting or Conforming Laws or Regulations. Most Cited Cases  
Presumption against federal preemption of state laws applies in conflict preemption cases. U.S.C.A. Const. Art. 6, cl. 2.

## [12] States 360 ⚡ 18.11

### 360 States

#### 360I Political Status and Relations

#### 360I(B) Federal Supremacy; Preemption

#### 360k18.11 k. Congressional Intent. Most Cited Cases

Even when presumption against federal preemption of state law applies, it will be overcome when a congressional purpose to preempt or the existence of a conflict is clear and manifest. U.S.C.A. Const. Art. 6, cl. 2.

## [13] States 360 ⚡ 18.9

### 360 States

#### 360I Political Status and Relations

#### 360I(B) Federal Supremacy; Preemption

360k18.9 k. Federal Administrative Regulations. Most Cited Cases  
Agency's informal views on issue of federal preemption of state-law claims are entitled to a respect proportional to their power to persuade; such an informal interpretation claims the merit of its writer's thoroughness, logic and expertness, its fit with prior interpretations, and any other sources of weight.

## [14] Food 178 ⚡ 25.2

### 178 Food

#### 178k25 Liability for Injuries

178k25.2 k. What Law Governs. Most Cited Cases

## States 360 ⚡ 18.65

### 360 States

#### 360I Political Status and Relations

#### 360I(B) Federal Supremacy; Preemption

360k18.65 k. Product Safety; Food and

### Drug Laws. Most Cited Cases

Consumer advisory published by Food and Drug Administration (FDA) regarding risks of mercury in fish and "backgrounder" for advisory that provided further information about mercury risks were not agency interpretations of regulations claimed to preempt state law, but rather were agency actions claimed to preempt state law, and thus were not entitled to deference from court in deciding whether federal law preempted consumer's claims under New Jersey Products Liability Act (NJPLA) based on failure of manufacturer of tuna products to warn of risks incurred in consuming its products; advisory and "backgrounder" offered no interpretation to which court could defer. N.J.S.A. 2A:58C1 et seq.

## [15] Food 178 ⚡ 15

### 178 Food

#### 178k11 Violations of Regulations

178k15 k. Misbranding or Want of Notice to Purchasers or Public. Most Cited Cases

## Food 178 ⚡ 16

### 178 Food

178k16 k. Penalties and Actions Therefor. Most Cited Cases

## States 360 ⚡ 18.65

### 360 States

#### 360I Political Status and Relations

#### 360I(B) Federal Supremacy; Preemption

360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases

Although, in determining whether federal law preempted consumer's state-law claims against producer of tuna products based on its failure to warn of mercury risks, courts had to consider views expressed in letter that was sent by Food and Drug Administration (FDA) to California's attorney general, opining that FDA's prior regulatory actions preempted California's lawsuit for injunction and civil penalties against producer and others for failing to warn consumers that their tuna products had dangerous

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mercury compounds, letter was not persuasive, so as to merit deference; FDA's views in letter, and significance attributed to its prior actions, were not shown to be product of agency proceeding, were not expressed at time actions were taken or when consumer's damages allegedly arose, and were not self-evident from nature of actions themselves, and reasoning itself was unpersuasive.

#### [16] Administrative Law and Procedure 15A ⚡741

15A Administrative Law and Procedure

15AV Judicial Review of Administrative Decisions

15AV(D) Scope of Review in General

15Ak741 k. In General. Most Cited Cases

Weight accorded by court to administrative judgment in a particular case will depend upon the thoroughness evident in judgment's consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control.

#### [17] Food 178 ⚡25.2

178 Food

178k25 Liability for Injuries

178k25.2 k. What Law Governs. Most Cited Cases

#### States 360 ⚡18.65

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases

Food and Drug Administration (FDA) had not adopted regulatory scheme respecting mercury in tuna products of a type that could conflict with, and thus preempt, consumer's state-law claims under New Jersey Products Liability Act (NJPLA) based on manufacturer's failure to warn of risks in consuming its products, given that FDA had not promul-

gated pertinent legal standard pertaining either to risks posed by mercury in fish or to warnings for that risk, and had not otherwise acted on issue in manner that could be deemed exclusive application of federal law; FDA's advisory and "background," which offered advice and recommendations to consumers, did not specifically regulate levels of methylmercury in tuna or specifically reject notion that warning labels be included on tuna cans, and internal enforcement guideline could not alone preempt state law. U.S.C.A. Const. Art. 6, cl. 2; Federal Food, Drug, and Cosmetic Act, §§ 401, 406, 21 U.S.C.A. §§ 341, 346; N.J.S.A. 2A:58C1 et seq.

#### [18] Food 178 ⚡25.2

178 Food

178k25 Liability for Injuries

178k25.2 k. What Law Governs. Most Cited Cases

#### States 360 ⚡18.65

360 States

360I Political Status and Relations

360I(B) Federal Supremacy; Preemption

360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases

Even if Food and Drug Administration (FDA) guideline recommending enforcement action if methylmercury levels in tuna products exceeded certain level was deemed to be federal regulatory standard, regulation did not conflict with, so as to preempt, consumer's claims under New Jersey Products Liability Act (NJPLA) based on manufacturer's failure to warn of risks incurred in consuming its tuna products, given that guideline was consistent with, and arguably complementary to, consumer's claims, and did not state that tuna with lower mercury levels posed no risk or that manufacturer met its standard of care if its tuna satisfied guideline. U.S.C.A. Const. Art. 6, cl. 2; N.J.S.A. 2A:58C1 et seq.

#### [19] Food 178 ⚡25.2

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178 Food  
 178k25 Liability for Injuries  
 178k25.2 k. What Law Governs. Most Cited Cases

**States 360 ⚡ 18.65**

360 States  
 360I Political Status and Relations  
 360I(B) Federal Supremacy; Preemption  
 360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases  
 Food and Drug Administration (FDA) did not promulgate binding regulatory scheme implementing any federal decision to leave unregulated the risk posed by mercury in tuna products, so as to preclude state duty on part of manufacturers of tuna products to warn consumers of risk of mercury in tuna, and FDA could not institute such a regime via informal expressions of policy, and therefore actual conflict required for preemption did not exist between federal law, based on FDA's purported decision not to regulate, and consumer's claims under Jersey Products Liability Act (NJPLA) based on manufacturer's failure to warn consumers about mercury in its products. U.S.C.A. Const.Art. 6, cl. 2; N.J.S.A. 2A:58C1 et seq.

**[20] States 360 ⚡ 18.5**

360 States  
 360I Political Status and Relations  
 360I(B) Federal Supremacy; Preemption  
 360k18.5 k. Conflicting or Conforming Laws or Regulations. Most Cited Cases  
 State law is not preempted whenever an agency has merely "studied" or "considered" an issue; state law is preempted when federal law conflicts with state law. U.S.C.A. Const. Art. 6, cl. 2.

**[21] Food 178 ⚡ 25.2**

178 Food  
 178k25 Liability for Injuries  
 178k25.2 k. What Law Governs. Most Cited Cases

**States 360 ⚡ 18.65**

360 States  
 360I Political Status and Relations  
 360I(B) Federal Supremacy; Preemption  
 360k18.65 k. Product Safety; Food and Drug Laws. Most Cited Cases  
 No actual conflict existed between consumer's claims, under Jersey Products Liability Act (NJPLA), alleging that manufacturer failed to warn consumers regarding mercury in its tuna products and misbranding regulatory authority of Food and Drug Administration (FDA) under Food, Drug and Cosmetics Act (FDCA), so as to preempt consumer's state-law claims, given that FDA had taken no regulatory action establishing mercury warnings as misbranding under federal law, and that regulatory concerns which FDA had expressed informally did not conflict with consumer's claims such that manufacturer would have been unable to provide warning that satisfied both its alleged state-law duty and FDA's concerns. U.S.C.A. Const. Art. 6, cl. 2; Federal Food, Drug, and Cosmetic Act, §§ 301(a, b), 302, 303, 305, 403(a), 21 U.S.C.A. §§ 331(a, b), 332, 333, 335, 343(a); 21 C.F.R. § 1.21; N.J.S.A. 2A:58C1 et seq.

**West Codenotes**

Recognized as PreemptedWest's Ann.Cal.Health & Safety Code § 25249.6  
 Kenneth A. Schoen, Scott H. Goldstein, Bonner, Kiernan, Trebach & Crociata, Parsippany, NJ, John A. Kiernan (Argued), Bonner, Kiernan, Trebach & Crociata, Boston, MA, Attorneys for Appellee.  
 William O. Crutchlow, Khalid Elhassan, Eichen, Levinson & Crutchlow, Edison, NJ, Adina H. Rosenbaum (Argued), Brian Wolfman, Public Citizen Litigation Group, Washington, DC, Attorneys for Appellant.

Before: SLOVITER, SMITH and STAPLETON, Circuit Judges.

**OPINION OF THE COURT**



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STAPLETON, Circuit Judge:

\*1 Plaintiff Deborah Fellner filed this lawsuit against defendant Tri-Union Seafoods, LLC ("Tri-Union") in the Superior Court of New Jersey seeking damages for harm she allegedly sustained as a result of her consumption of methylmercury and other harmful compounds contained in Tri-Union's tuna fish products. The case was removed to federal court, and Tri-Union filed a motion to dismiss for failure to state a claim asserting that Fellner's lawsuit is preempted by regulatory actions of the United States Food and Drug Administration ("FDA"). The District Court granted the motion, ruling that Fellner's claims are preempted by the FDA's "regulatory approach" to the risks posed by mercury compounds in tuna fish. Because we conclude that the FDA has taken no regulatory action which preempts Fellner's lawsuit, we will reverse and remand for further proceedings.

### I. Facts and Procedural Background

Fellner alleges that Tri-Union produces, cans and distributes Chicken-of-the-Sea brand tuna fish and that, from 1999 to 2004, her diet consisted almost exclusively of TriUnion's tuna products. She further avers that those products contained methylmercury and other harmful compounds that can result in mercury poisoning and that "[d]ue to the negligence and statutory violations of the Defendant ... Fellner contracted severe mercury poisoning and suffered extreme physical and emotional injuries." App. at 30a, ¶ 28. She seeks recovery under the New Jersey Products Liability Act, N.J.S.A. 2A:58C1, *et seq.* ("NJPLA"), based on Tri-Union's failure to warn of the risks incurred in consuming its products.<sup>FN1</sup>

The factual landscape of this case is colored by recent litigation in California. On June 21, 2004, then-Attorney General of California, Bill Lockyer, filed a lawsuit against TriUnion and other defendants under California's "Proposition 65," CAL. HEALTH & SAFETY CODE § 25249.6, seeking an injunction and civil penalties for defendants' failure to warn consumers that their tuna products

contain dangerous mercury compounds. While that suit was pending, the Commissioner of the FDA sent a letter to Mr. Lockyer expressing the opinion that the FDA's prior regulatory actions preempt the State's lawsuit. In the Commissioner's view, the defendants would be unable to comply both with that approach and state law and the existence of the lawsuit would "frustrate the [FDA's] carefully considered federal approach" to the issue of mercury in fish. *See People v. Tri-Union Seafoods*, 2006 WL 1544377 (Cal.Super.Ct. May 12, 2006) (taking judicial notice of the letter). In May 2006, following a bench trial, the Superior Court of California found the Attorney General's lawsuit preempted by federal law. *People v. TriUnion Seafoods*, 2006 WL 1544384 (Cal.Super.Ct. May 11, 2006), *appeal docketed*, No. A116792 (Cal.Ct.App. 1st Dist. Feb. 20, 2007).

Tri-Union removed Fellner's lawsuit to the United States District Court for the District of New Jersey and filed a motion to dismiss for failure to state a claim accompanied by motions requesting that the Court take judicial notice of four documents: (1) a consumer advisory published by the FDA in 2004 regarding the risks of mercury in fish ("the Advisory"); (2) a "backgrounder" for the FDA's 2004 Advisory, which provides further information about those risks ("the backgrounder"); (3) Section 504.0600 of the FDA's Compliance Policy Guide, a guideline recommending that the FDA initiate enforcement action if the concentration of mercury in fish exceeds "1 ppm" ("the Compliance Guide"); and (4) the above-described letter sent by the Commissioner of the FDA to the Attorney General of California ("the Commissioner's letter").

\*2 The District Court took judicial notice of the four documents submitted by defendant and granted defendant's motion to dismiss. *Fellner v. Tri-Union Seafoods*, 2007 WL 87633 (D.N.J.2007). It found that the FDA had implemented a "pervasive regulatory scheme" pertaining to the risks of methylmercury in fish consisting of the FDA's Advisory, backgrounder, Compliance Guide, and the

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Commissioner's letter. It concluded that the FDA had deliberately declined to require warnings in favor of a more "nuanced" and "balanced" approach consisting of targeted advisories, and that the state law duties relied upon by Fellner in her lawsuit would upset that approach. As a result, the Court dismissed the complaint, holding that the FDA's regulatory scheme regarding mercury in fish preempts Fellner's state law claims. She timely appealed.

## II. Jurisdiction and Standard of Review

[1][2] We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review of the District Court's order granting defendant's motion to dismiss. *Santiago v. GMAC Mortgage Group*, 417 F.3d 384, 386 (3d Cir.2005). When reviewing a motion to dismiss for failure to state a claim under Fed.R.Civ.P. 12(b)(6), we accept as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them, and we affirm the order of dismissal only if the pleading does not plausibly suggest an entitlement to relief. *Wilkerson v. New Media Tech. Charter Sch.*, 522 F.3d 315, 321-22 (3d Cir.2008).

## III. Discussion

The sole question presented in this appeal is whether Fellner's state claim for damages is preempted by federal law. Tri-Union offers three distinct theories of preemption: (1) that the FDA has adopted a "pervasive regulatory approach"-embodied in the FDA's Advisory, background and internal enforcement guideline-with which Fellner's state lawsuit actually conflicts; (2) that the FDA has "reject[ed] the use of warning labels" in favor of a more "nuanced" approach-that is, that the FDA has reached a decision that warnings should not be regulated, a decision which preempts the state from entertaining a claim based on a duty to warn theory; and (3) that the FDA would have rejected any warning as "misbranding," a determination which

preempts Fellner's failure-to-warn claim.

### A. The Doctrine of Federal Preemption

[3] The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, which invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 712, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1 (9 Wheat. 1, 211), (1824)). As we recently explained,

[t]he Supreme Court has identified three major situations where there is preemption ... (1) "express" preemption, applicable when Congress expressly states its intent to preempt state law; (2) "field" preemption, applicable when "Congress' intent to pre-empt all state law in a particular area may be inferred [because] the scheme of federal regulation is sufficiently comprehensive" or "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" and (3) "conflict" preemption, applicable when "state law is nullified to the extent that it actually conflicts with federal law," even though Congress has not displaced all state law in a given area.

\*3 *Colacicco v. Apotex Inc.*, 521 F.3d 253, 261 (3d Cir.2008) (quoting *Hillsborough County*, 471 U.S. at 713, 105 S.Ct. 2371). See also *English v. General Elec. Co.*, 496 U.S. 72, 78-79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990) (summarizing the three types of preemption). Tri-Union has not argued, nor could it, that Fellner's lawsuit is expressly preempted by the Food, Drug and Cosmetics Act ("FDCA") or by federal regulation.<sup>FN2</sup> Similarly, we do not interpret TriUnion's brief as asserting a field preemption claim, and any such claim would be unavailing.<sup>FN3</sup> If preemption exists in this case it must be conflict preemption.

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[4][5] As the Supreme Court frequently reiterates, in all cases “preemption fundamentally is a question of congressional intent.” *English*, 496 U.S. at 78-79, 110 S.Ct. 2270. See also *Medtronic v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (“[t]he purpose of Congress is the ultimate touchstone” in every preemption case”) (citation omitted). However, “state laws can be preempted by federal regulations as well as by federal statutes.” *Hillsborough County*, 471 U.S. at 713, 105 S.Ct. 2371. Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency’s regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency’s delegated authority. *Fidelity Fed. Savings and Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153-54, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982).

[6] Although federal administrative law as well as Congressional enactments are the supreme law of the land, we must reiterate, lest the analysis become unmoored, that it is federal law which preempts contrary state law; nothing short of federal law can have that effect. The Supreme Court’s longstanding interpretation of the Supremacy Clause, and indeed the Supremacy Clause itself, mandate this principle:

Article VI of the Constitution provides that the laws of the United States “shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any states to the Contrary notwithstanding.” Art. VI, cl.2. Thus, since our decision in *M’Culloch v. Maryland*, it has been settled that state law that conflicts with federal law is “without effect.”

*Cipollone*, 505 U.S. at 516, 112 S.Ct. 2608 (emphasis added). See also *Colacicco*, 521 F.3d at 261 (“[e]arly in our constitutional history, the Supreme Court interpreted this language to invalidate state laws that ‘interfere with, or are contrary to,’ federal law, the genesis of the preemption doctrine”) (emphasis added; citation omitted).

[7] As we have noted, there is no doubt that federal regulations as well as statutes can establish federal law having preemptive force. *New York v. Fed. Comm’n Comm’n*, 486 U.S. 57, 63, 108 S.Ct. 1637, 100 L.Ed.2d 48 (1988) (“The phrase ‘Laws of the United States’ [in the Supremacy Clause] encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization”). Although there is some authority for the proposition that the only regulatory process which can produce “federal law” for purposes of the Supremacy Clause is formal, notice and comment rulemaking, *Good v. Altria Group*, 501 F.3d 29, 51-52 (1 st Cir.2007), cert. granted, --- U.S. ---, 128 S.Ct. 1119, 169 L.Ed.2d 846 (2008) (collecting cases), we have joined those courts which hold that, in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law. *Colacicco*, 521 F.3d at 271 (citations omitted).

\*4 [8] It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute “federal law” under the Supremacy Clause: “[i]t is well established that when developing law on a subject, an agency usually has a choice between the method of rulemaking and that of adjudication,” *General Motors Corp. v. Abrams*, 897 F.2d 34, 39 (2d Cir.1990) (citation omitted); both agencies’ quasi-legislative as well as their quasi-judicial powers “have the binding force of ‘federal law.’” *Id.* (citation omitted). See also *Chicago and Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 314-15, 321-28, 101 S.Ct. 1124, 67 L.Ed.2d 258 (1981) (Interstate Commerce Commission order following quasi-judicial proceeding governing abandonment of rail lines preempted state law). Moreover, in addition to orders from formal adjudicatory proceedings, we have recently given preemptive effect to a federal agency order in a similar situation where a comprehensive federal regulatory scheme authorized a process for the agency to apply a federal standard to concrete cir-



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cumstances, and it had utilized that process in a manner establishing a federal duty or policy. In *Colacicco*, the plaintiffs' alleged claims for failure to warn that a family of drugs used to treat anxiety and depression caused an increased risk of suicidality. The FDCA conferred jurisdiction upon the FDA to regulate drug labeling. Regulations authorized by the FDCA predicated the marketing of drugs on FDA approval of the drugs' labeling both at the time the drugs were initially marketed and on an ongoing basis thereafter. Defendants' labels had received FDA approval both before and after the suicides at issue. The plaintiffs pointed out, however, that the regulations required that the labeling be revised by the manufacturer unilaterally "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.57(c) (2003). Plaintiffs argued that this meant the defendants could have complied with both the federal regulations and the state duty to warn, and thus no conflict existed. We rejected this argument because, although the regulations allowed a manufacturer to amend warnings unilaterally, all such amendments remained contingent on the manufacturer ultimately receiving FDA approval, and the FDA in a number of different agency proceedings had previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject suicidality warnings based on that evidence. The FDA had "clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue...." *Colacicco*, 521 F.3d at 271. Although defendants had not been shown to be participants in those proceedings, we concluded that a conflict existed because, much like agency quasi-judicial proceedings, see *Securities and Exchange Commission v. Chenery Corp.*, 332 U.S. 194, 201-03, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947), the FDA's actions in those proceedings established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances, such as the defendants. Thus, defendants could not have complied with the requirements

of both federal and state law.

\*5 [9] This does not mean, however, that federal law capable of preempting state law is created every time someone acting on behalf of an agency makes a statement or takes an action within the agency's jurisdiction. As the Supreme Court has explained, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001) (addressing which types of agency actions should be afforded *Chevron* deference). We believe that similar considerations are pertinent here. We decline to afford preemptive effect to less formal measures lacking the "fairness and deliberation" which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law. Courts with good reason are wary of affording preemptive force to actions taken under more informal circumstances. See, e.g., *Good*, 501 F.3d at 51-52; *Wabash Valley Power Assn. v. Rural Elec. Admin.*, 903 F.2d 445, 453-54 (7th Cir.1990); *General Motors Corp.*, 897 F.2d at 39. Regularity of procedure—whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a particular purpose—not only ensures that state law will be preempted only by federal "law," as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.

Tri-Union points to the Commissioner's letter as both establishing federal law capable of preemption and as evidencing the agency's interpretation of previously established law, an interpretation to which we should defer. We evaluate below the deference to which we believe that letter is entitled as

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an interpretation of pre-existing federal law. With respect to Tri-Union's claim that it established federal law, we note that we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption. See *Wabash Valley*, 903 F.2d at 453-54 (declining to give preemptive effect to an agency letter where the prescribed procedures were not followed); *Thomas v. New York*, 802 F.2d 1443 (D.C.Cir.1986) (same).FN4

Finally, the Supreme Court occasionally has confronted a claim that a federal agency's decision not to regulate should be granted preemptive effect because it constitutes a federal determination that the issue shall be *unregulated*-here, the decision not to require (or otherwise regulate) mercury warnings. As the Court explained, "a federal decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left *unregulated*, and in that event would have as much preemptive force as a decision to regulate." *Ark. Elec. Co-op. v. Ark. Pub. Serv.*, 461 U.S. 375, 384, 103 S.Ct. 1905, 76 L.Ed.2d 1 (1983) (emphasis in original).

\*6 However, the Supreme Court has since cautioned that this statement in *Arkansas Electric Co-op* "was obviously not meant in an unqualified sense; otherwise, deliberate federal inaction could always imply preemption, which cannot be. There is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it." *P.R. Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503, 108 S.Ct. 1350, 99 L.Ed.2d 582 (1988). The Court further explained,

[w]e are presented with the decidedly untypical claim that federal pre-emption exists despite not only the absence of a statutory provision specifically announcing it, but the absence of any extant federal regulatory program with which the state regulation might conflict and which might therefore be thought to imply pre-emption."

*Id.* at 500, 108 S.Ct. 1350. The Court rejected the claim, concluding that "unenacted approvals, beliefs, and desires are not laws. Without a text that can, in light of those statements, plausibly be interpreted as *prescribing* federal pre-emption it is impossible to find that a free market was mandated by federal law." *Id.* at 501, 108 S.Ct. 1350 (emphasis in original).

The Court again confronted, and rejected, a similar claim just a few years ago. Although the Court acknowledged that the agency had the authority to enact a regime free of any regulation concerning the risk at issue, it declined to infer such a regime from a mere decision not to regulate, absent an " 'authoritative' message of a federal policy against [regulation]." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67, 123 S.Ct. 518, 154 L.Ed.2d 466 (2002). The Court explained,

[i]t is quite wrong to view [the Coast Guard's decision not to adopt a regulation] as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation.... Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur. This, however, is not such a case.

*Sprietsma*, 537 U.S. at 65, 123 S.Ct. 518 (emphasis added).FNS

[10] *Isla Petroleum* and *Sprietsma* make clear that mere deliberate agency inaction-an agency decision *not* to regulate an issue-will not alone preempt state law. Furthermore, we find no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force; in all cases concerning alleged "federal determination[s] that [an] area is best left *unregulated*," *Ark. Elec. Co-op.*, 461 U.S. at 384, 103 S.Ct. 1905, the Supreme Court and Courts of Appeals have inquired whether some ex-

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tant law or regulation evinced an “authoritative message of federal policy” that an issue is to remain free of state regulation (or any regulation at all); “unenacted approvals, beliefs, and desires” will not suffice.<sup>FN6</sup>

### **B. Presumption Against Preemption and Deference to the Agency**

\*7 The parties dispute the applicability of two familiar rules of interpretation. Fellner asserts that we should apply a presumption against preemption. Tri-Union asserts that Fellner's reliance on the presumption against preemption is misplaced, and that in fact we should afford deference to the agency's views on preemption.

#### **1. Presumption Against Preemption**

The Supreme Court historically has applied a presumption against the preemption of state laws:

because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has “legislated ... in a field which the States have traditionally occupied,” we “start with the assumption that the historic police powers of the States were not superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”

*Medtronic v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (citations omitted). See also *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (“[w]here ... the field that Congress is said to have pre-empted has been traditionally occupied by the States ‘we start with the [presumption];’”) (citation omitted); *Bates*, 544 U.S. at 449, 125 S.Ct. 1788 (similar).

Recent Supreme Court jurisprudence suggests that

the presumption remains applicable when preemption claims concern areas of the law “which the States have traditionally occupied,” but that it may not be applicable “where the interests at stake are ‘uniquely federal’ in nature.” *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (declining to apply the presumption because “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied’.... To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character”) (citations omitted). See also *United States v. Locke*, 529 U.S. 89, 108, 120 S.Ct. 1135, 146 L.Ed.2d 69 (2000) (presumption applies “in field[s] which the states have traditionally occupied,” but declining to apply it because “national and international maritime commerce” is not such a field) (citations omitted).

In the present case, it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product. See, e.g., *Bates*, 544 U.S. at 449, 125 S.Ct. 1788 (“The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption”). Furthermore, state tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case. Federal regulatory programs frequently do not include a compensatory apparatus, and the Supreme Court has recognized that state tort law can also play an important information-gathering role not easily replicated by federal agencies.<sup>FN7</sup> When a litigant asserts that a private right of action, as opposed to a state statute or regulation, is preempted, we are cognizant that preemption may leave individuals with rights but no private remedy, where traditionally there has been one. Although Congress certainly can afford, and in some instances has afforded, federal regulators exclusive jurisdiction over a particular subject matter, and federal regula-

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tions will preempt state laws that actually do conflict with them, we do not lightly infer such a result where state compensatory regimes have traditionally played an important role.

\*8 [11][12] Although we are aware that the Supreme Court has applied the presumption in few conflict preemption cases of late, and arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption, *see Colacicco*, 521 F.3d at 265, we will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary. *Id.* See also *Hillsborough County*, 471 U.S. at 715, 105 S.Ct. 2371 (applying the presumption to implied preemption claims). However, even where the presumption applies it will be overcome where a Congressional purpose to preempt or the existence of a conflict is "clear and manifest." *Id.*

## 2. Deference to Federal Agency Views

Tri-Union argues that "the FDA's findings and opinion set forth in the FDA Preemption Letter as well as its regulatory approach (the FDA Advisory and Backgrounder) should be afforded a high level of deference and/or persuasion." Appellee's Br. at 24.

[13] As we recently explained, "[w]e would ordinarily be leery of an agency's view of what is essentially a legal issue," *Colacicco*, 521 F.3d at 274, but in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), the Supreme Court "place[d] some weight," on the agency's informal views of the purposes and objectives of the regulation at issue and the agency's view that the state lawsuit would "stand as an obstacle" to those objectives. *Id.* at 883, 120 S.Ct. 1913. We concluded that "such a position is subject to a level of deference approximating that set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 [ ] (1944)." *Colacicco*, 521 F.3d at 275. As with *Skidmore* deference, the agency's informal views are entitled to "a respect proportional

to [their] 'power to persuade'.... [Such informal interpretations] claim the merit of its writer's thoroughness, logic and expertness, [their] fit with prior interpretations, and any other sources of weight." *Mead Corp.*, 533 U.S. at 235, 121 S.Ct. 2164 (citation omitted). However, *Geier* does not suggest that courts abdicate their duty to examine whether federal and state law actually conflict. *Geier* did not rely exclusively on the agency's views, explaining that it found the conflict "clear enough" even absent those views. *Geier*, 529 U.S. at 886, 120 S.Ct. 1913.

[14] The District Court concluded that "the FDA's Advisory and Backgrounder are entitled to deference and [ ] the FDA Letter is persuasive." *Fellner v. Tri-Union Seafoods*, 2007 WL 87633, \*7 (D.N.J.2007). *Geier* and cases applying it have afforded some weight to an agency's informal interpretation of the purposes and objectives of its regulations which are claimed to preempt state law. However, the FDA's Advisory and backgrounder are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law. We fail to understand how a court could defer to those documents; they offer no interpretation to which we can defer.

\*9 [15][16] The FDA (indirectly) has offered its interpretation of the purposes and objectives of the regulatory measures at issue in this case in the Commissioner's letter. We agree with the District Court that *Geier* directs us to consider the views expressed in that letter and, as we have explained, those views are entitled to consideration proportional to their ability to persuade: "The weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control." *Mead Corp.*, 533 U.S. at 228, 121 S.Ct. 2164 (quoting *Skidmore*, 323 U.S. at 140, 65 S.Ct.



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161) (bracketed text in original). Here, however, we do not find the letter persuasive. The circumstances of this letter suggest that it merits a particularly low level of deference. The views the FDA there offers, and the significance it there attributes to its prior administrative actions, have not been shown to be the product of any agency proceeding,<sup>FNS</sup> were not expressed at the time those actions were taken nor even at the time that Fellner's damages allegedly arose, and are certainly not self-evident from the nature of the actions themselves. The FDA expressed those views only later, through a most informal of methods—a letter offering a legal theory for the litigation in California. Most importantly, we simply do not find the letter's reasoning persuasive, for the reasons we set forth below.

### C. Tri-Union's Three Theories of Conflict Preemption

As we have explained, this is a conflict preemption case. Therefore, Fellner's state law claims will be impliedly preempted if they are “in actual conflict with federal law.” *Sprietsma*, 537 U.S. at 64, 123 S.Ct. 518. The Supreme Court has identified two varieties of “conflict” preemption: (1) where “it is impossible for a private party to comply with both state and federal requirements,” and (2) where “state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *English*, 496 U.S. at 79, 110 S.Ct. 2270 (internal quotation marks and citations omitted).

We begin our analysis by taking note of the authority that Congress has bestowed on the FDA and the extent to which it has exercised that authority in a relevant manner. The FDCA grants the FDA authority to regulate the field of food safety. 21 U.S.C. § 371. The FDA has the authority, *inter alia*, to promulgate food definitions and standards of food quality, *id.* at § 341, and to set tolerance levels for poisonous substances in food. *Id.* at § 346. The FDA is also delegated enforcement authority, including the authority to take various steps to en-

force the Act's ban on “adulterated” or “misbranded” food. *Id.* at §§ 331-336, 342-343. The FDA has, however, promulgated no pertinent regulations under this authority. Nevertheless, it has employed various other means to address the risk of mercury in fish, including issuing a consumer advisory and related “backgrounder” regarding those risks, and including in its internal Compliance Guide a provision recommending that the agency initiate enforcement action if mercury concentrations in fish exceed a specified level. TriUnion offers three theories of conflict preemption based on these actions.

#### 1. Theory 1: Conflict with a Federal Regulatory Scheme

\*10 [17] Tri-Union first argues that the FDA has adopted a “pervasive regulatory approach” with which Fellner's lawsuit actually conflicts. Appellee's Br. at 13, 18-20. This argument suffers from two infirmities. First, as we have explained, state law is preempted only by federal law. The FDA has promulgated no pertinent legal standard pertaining either to the risks posed by mercury in fish or to warnings for that risk, and it has not otherwise acted on the issue in a manner that could be deemed an exclusive application of federal law. Second, even accepting *arguendo* the FDA's “regulatory scheme” were of a type that could preempt state law, Tri-Union has identified no actual conflict between Fellner's claims and the pertinent FDA actions.

We cannot agree with the District Court that the FDA's Advisory and backgrounder “specifically regulate[ ]” the levels of methylmercury in tuna and “specifically rejected the notion that warning labels should be included on cans of tuna.” *Fellner*, 2007 WL 87633 at \*4. That Advisory, titled “What You Need to Know About Mercury in Fish and Shellfish,” and the related backgrounder, offer “[a]dvice” for “women who might become pregnant[,] women who are pregnant[,] nursing mothers[,] and] young children,” App. at 35a, and



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provide “3 recommendations for selecting and eating fish” that such people are advised to follow. *Id.* We are unable to conclude that the Advisory and backgrounder “specifically regulate[ ]” anything—they simply give non-binding advice to a class of consumers and do not promulgate a federal legal standard with which Fellner’s state law claims could potentially conflict.

Fellner’s lawsuit does not conflict with the “advice” in those documents—the concerns expressed therein are entirely consistent with, and arguably complementary to, a duty state law may impose on manufacturers to warn consumers of the risks posed by tuna consumption. *See Bates*, 544 U.S. at 449-51, 125 S.Ct. 1788. The mere fact that the FDA chose to warn only certain “at risk” consumers, rather than all consumers, does not create a conflict. Nothing in these documents indicates that consumers other than those “at risk” individuals are *not* at risk of harm from mercury in fish or that they should *not* be warned. The Advisory does recommend continued fish consumption within certain parameters, but that recommendation is clearly not inconsistent with a warning against excess consumption.

Tri-Union also points to the FDA’s internal enforcement guideline suggesting mercury levels which might prompt FDA enforcement action, and the District Court similarly referenced an FDA “tolerance level” of “1 ppm.” *Fellner*, 2007 WL 87633 at \*2. *See* FDA Compliance Policy Guide, Section 540.600.<sup>FN9</sup> Based on this guideline, Tri-Union argues that “[t]he FDA has determined that there is no hazard associated with methylmercury concentrations of less than 1 ppm.” Appellee’s Br. at 37. We find no such determination. Although the FDA has authority to promulgate standards for food quality and tolerance levels for poisonous foods, 21 U.S.C. §§ 341, 346, it has not done so. The internal guideline for allocation of agency resources “recommend[ed]” in the Compliance Policy Guide will not alone preempt state law.

\*11 [18] Furthermore, even if this guideline were deemed a federal standard, Tri-Union fails to ex-

plain how Fellner’s lawsuit would conflict with it. The guideline states that the FDA may recommend enforcement action if methylmercury concentrations in fish exceed “1 ppm.” Much like the Advisory, the guideline appears entirely consistent with, and arguably complementary to, a state claim that Tri-Union wrongfully failed to warn consumers of the risks posed by those compounds. We are aware of no facts establishing the precise mercury concentrations in Tri-Union’s tuna products. Even if Fellner had alleged a specific concentration lower than the FDA guideline—for example, if Fellner had specifically averred that Tri-Union’s tuna was dangerous because it contained mercury at a concentration of 0.7 ppm—such a claim would not necessarily be in conflict with this federal “standard.” On its face the guideline does not state that tuna with mercury levels below 1 ppm poses no risk nor that a manufacturer has met any particular standard of care if its tuna does not exceed 1 ppm; it merely suggests that the FDA recommend enforcement action if mercury levels exceed 1 ppm.<sup>FN10</sup>

In support of its “pervasive regulatory approach” argument, Tri-Union also points to the Commissioner’s letter, in which the Commissioner explains that the FDA prefers to address the risks of mercury in fish through advisories rather than warnings requirements due to the risk of overexposure to warnings and the agency’s desire to promote moderate fish consumption. We presume that this is a fair concern. However, the FDA has not acted to regulate it in a manner that could preempt Fellner’s claims. As we have explained, the letter itself does not establish a federal policy against warnings capable of preempting state law. As we have also explained, we do not find persuasive the letter’s characterization of the FDA’s prior actions on the subject as a “regulatory scheme” capable of preempting Fellner’s claims.

We conclude that the FDA has regulated neither the risk of mercury in tuna nor the permissible warnings regarding that risk in a manner that conflicts with Fellner’s lawsuit.

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## 2. Theory 2: A Federal Decision Not To Regulate

[19] Tri-Union's second theory of preemption is that the FDA has "reject [ed] the use of warning labels," Appellee's Br. at 32-that the FDA reached a "federal decision to forego regulation" amounting to "an authoritative federal determination that the area is best left *unregulated*," a decision which preempts any state standard or duty requiring such warnings. *Id.* at 31 (quoting *Ark. Elec. Co-op.*, 461 U.S. at 384, 103 S.Ct. 1905) (emphasis in original). In Tri-Union's view, just such a decision was made when the Commissioner's letter was dispatched. In that letter, the Commissioner expressed the view that, because the FDA after "studying the issue of methylmercury in fish for several years," App. at 42a, declined to require a warning and instead issued an advisory, the California lawsuit would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *Id.* Although the federal government certainly may promulgate a regulatory regime in which it decides that a particular issue is best left unregulated, as the Supreme Court has explained, "to say that [such a regime] can be created is not to say it can be created subtly." *Isla Petroleum*, 485 U.S. at 500, 108 S.Ct. 1350. A mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn, and, as we have earlier indicated, we find no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warnings obligations via mere informal expressions of policy such as those in the Commissioner's letter. *Id.* at 501, 503, 108 S.Ct. 1350 ("[t]here is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it;" "unenacted approvals, beliefs, and desires are not laws").

\*12 While the FDA may well have the authority to promulgate a regulatory scheme which would preclude any state duty to warn consumers of the risks of mercury in tuna, it simply has not done so. Tri-Union points to the Commissioner's letter, but as

we have explained courts have declined to permit agencies to promulgate express preemption decisions by informal letter. In any event, we do not read the letter as purporting to declare a new preemption policy; it purports to be an explanation of what the FDA determined to do in the past. As we have indicated, however, nothing in the agency's past actions indicates that it made an "authoritative federal determination that the area is best left unregulated."

[20] We have no reason to doubt that the FDA has studied the risks of mercury in fish, as the District Court found. However, it made no "conclusive determination" of the sort which will preempt state law-neither that mercury in fish poses no adverse health consequences, nor to prohibit some or all warnings. State law is not preempted whenever an agency has merely "studied" or "considered" an issue; state law is preempted when federal *law* conflicts with state law. As we have explained, the cases leave no doubt that a mere decision not to regulate-in this case, a decision not to require a federal methylmercury warning-alone will not preempt state law. *See supra* note 6 and accompanying text. As we have also explained, we find no federal standard, mandate or regulatory action on the subject with which Fellner's claim conflicts nor any federal determination precluding state regulation of the issue.

## 3. Theory 3: The FDCA's Food Misbranding Provision

[21] Finally, Tri-Union contends that Fellner's failure-to-warn claim is preempted because that claim is premised on the theory that it should have provided a warning regarding mercury in fish, but the FDA would have deemed any such warning "misbranding," creating a conflict between the asserted state duty and federal law. Appellee's Br. at 33-37. Tri-Union argues that the FDA would deem a warning false and misleading because any such warning would not "specify the scientific basis as to the cause of the harm warned of, and/or the

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amounts of such food that were required to cause this harm,” Appellee’s Br. at 34-35, and because a warning would not “balance out the negative methylmercury information with positive information about the numerous healthy attributes of canned tuna,” *id.* at 35, resulting in overexposure to warnings and scaring consumers away from a useful product. *Id.* In support of this claim, TriUnion points to the Commissioner’s letter, in which the Commissioner opined that the “Proposition 65 warnings”-the warnings requirement underpinning the California Attorney General’s lawsuit-would be false or misleading for similar reasons.

The FDCA’s general misbranding provision for food provides, in pertinent part, that “[a] food shall be deemed misbranded-(a) False or misleading label[.]; If (1) its labeling is false or misleading in any particular....” 21 U.S.C. § 343(a). FDA regulations further provide that “labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device, or any combination thereof...” 21 C.F.R. § 1.21. The FDCA renders unlawful, *inter alia*, the misbranding of food and the distribution of misbranded food, *id.* at § 331(a)-(b), and it authorizes the FDA to enforce those prohibitions via enforcement actions in the United States District Courts for injunctions or criminal penalties. *Id.* at §§ 332, 333. The FDCA also delegates to the FDA certain additional tools to prevent misbranding. The FDA may, and indeed must, officially express its concerns with a warning or label before reporting a violation to a United States Attorney for criminal proceedings, to afford the regulated entity notice and an opportunity to present its views. *Id.* at § 335. In the case of “minor violations,” the agency may issue “a suitable written notice or warning.” *Id.* at § 336. The FDA is also delegated the authority affirmatively to regulate food labels and warnings.<sup>FN11</sup>

\*13 Had the FDA considered the factual basis for the alleged duty to warn and exercised its mis-

branding authority to establish that a warning based on that data would be false or misleading under federal law-not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it-our recent decision in *Colacicco* would govern and a state failure-to-warn lawsuit would be preempted. However, Tri-Union’s misbranding theory suffers from the same shortcomings as its prior theories: it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it *has* identified actually conflict with Fellner’s lawsuit.

The FDA has taken no misbranding action pertaining to the risk of mercury in tuna whatsoever. In the above-listed provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food-“a suitable written notice or warning,” an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and affirmative regulation.<sup>FN12</sup> However, the FDA has taken no action pursuant to this authority. Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after Fellner’s injuries were allegedly suffered. We need not decide at what point a particular warning becomes established as false and misleading for preemption purposes. Suffice it to say that the FDA must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law; the informal views expressed in the Commissioner’s letter will not preempt Fellner’s lawsuit.

Furthermore, as with its other preemption theories, TriUnion fails to identify an actual conflict between the FDA’s concerns and Fellner’s claims. We perceive no actual conflict between those concerns and Fellner’s lawsuit. Had Tri-Union wished to warn consumers of those risks, as Fellner alleges it should have, it is not apparent that Tri-Union would have been unable to do so in a manner that satisfied

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both the alleged state law duty and the FDA's concerns. For example, a warning certainly could have specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits. For these reasons, we find no actual conflict between the FDA's misbranding authority and Fellner's lawsuit.

#### IV. Conclusion

This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's "regulatory scheme" for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter. Fellner's duty-to-warn claim does not conflict with an FDA determination deliberately to forego warnings because the FDA took no action to preclude state warnings-at least, no binding action via ordinary regulatory procedures, and no action whatsoever until after Tri-Union allegedly wrongfully failed to warn. Finally, Fellner's lawsuit does not conflict with the FDCA's food misbranding provision or the FDA's actions thereunder because the FDA has not exercised its misbranding authority under the FDCA with respect to methylmercury warnings for fish.

\*14 The FDA has only issued a consumer advisory regarding the risks posed by mercury in fish and established a guideline regarding mercury concentrations to guide its enforcement decisions. Neither of these agency acts constitutes a federal legal standard or binding regulatory action on the subject which could give rise to a conflict, and indeed neither expresses a policy or viewpoint or approach inherently inconsistent with Fellner's lawsuit. In the final analysis, this case involves an agency effort to

preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred. We understand the precedent to require more of federal agencies to institute a policy expressly precluding state regulation than a mere informal letter, and neither the Commissioner's letter nor TriUnion's brief identifies any federal law with which Fellner's lawsuit might conflict. Although the Supremacy Clause provides that state laws will give way when they actually conflict with federal law, on this record we find no federal law with which the alleged state duty to warn conflicts.

For the foregoing reasons, we will reverse the judgment of the District Court and remand the case for further proceedings consistent with this opinion.

FN1. While the complaint refers to a design defect, we find it unclear whether the alleged design defect is the failure to warn or is a claim based on excessive mercury concentrations which is distinct from the failure to warn. The District Court apparently reached the former conclusion; it dismissed the failure-to-warn claim without addressing whether the complaint asserts a separate design-defect claim and whether any such claim is preempted. Due to this posture, and because our disposition of this appeal will result in remand to the District Court, we decline to address the design defect claim, if one there be, and instead will allow the parties to raise these issues before the District Court if they so choose.

FN2. The Act includes an express preemption provision, 21 U.S.C. § 343-1, but Tri-Union does not urge that it governs this case. The inclusion of express preemption provisions does not preclude the operation of ordinary implied preemption principles. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000).



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FN3. Courts rarely find field preemption, especially in areas traditionally regulated by the states, unless the structure of a regulatory program leaves little doubt that Congress intended federal law to be exclusive in a particular field. *See, e.g., Hillsborough County*, 471 U.S. at 717, 105 S.Ct. 2371 (“merely because the federal provisions [are] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field... We are even more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes ...”). In this case, the “regulatory scheme” identified by Tri-Union and the Commissioner’s letter fall far short of the sort of comprehensive federal program ordinarily addressed in field preemption cases.

FN4. Contrary to Tri-Union’s suggestion, we do not read *Geier* as indicating otherwise. Although *Geier* declined to require a “specific, formal agency statement identifying a conflict in order to conclude that [ ] a conflict in fact exists,” *Geier*, 529 U.S. at 884, 120 S.Ct. 1913, it did require that state law actually conflict with a federal law. The Court ruled that a state lawsuit was preempted because it actually conflicted with a Department of Transportation (“DOT”) regulation (FMVSS 208), *id.* at 874, 120 S.Ct. 1913, and the Court merely “place[d] some weight upon the DOT’s [informal] interpretation of FMVSS 208’s objectives ...,” *id.* at 883, 120 S.Ct. 1913, to help it determine whether the two in fact conflicted.

FN5. *Sprietsma* discussed the agency’s informal, contemporaneous explanation for its decision not to regulate and also em-

phasized that the agency had taken an anti-preemption position in briefings for the Court. *Sprietsma*, 537 U.S. at 67-68, 123 S.Ct. 518. We do not interpret *Sprietsma* to have implied that, had the agency adopted a pro-preemption stance in an informal statement or briefings for the Court, those views alone would have imbued the agency’s decision not to regulate with preemptive force. *Geier* directs that courts should consider any views expressed by the agency regarding the purposes and objectives of its actions claimed to preempt state law, and therefore it was only natural for *Sprietsma* to note the agency’s agreement. Furthermore, *Sprietsma* emphasized a “stark contrast” with *Geier*: unlike the case before it, in *Geier* it was not mere inaction or a “decision not to regulate” combined with informal agency views that preempted state law but rather a federal regulation (FMVSS 208) that promulgated the “affirmative policy judgment”-the “authoritative message of a federal policy”-with which the state lawsuit was found to conflict. *Id.* at 68, 123 S.Ct. 518 (internal quotation marks and citation omitted).

FN6. We find only two situations in which courts have given preemptive effect to decisions not to regulate. First, the Supreme Court has found deliberate federal inaction to preempt state law (so-called “negative preemption”) through what is essentially a field preemption analysis: “[w]here a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, *then* the preemptive inference can be drawn-not from federal inaction alone, but from inaction joined with action.” *Isla Petroleum Corp.*, 485 U.S. at 503, 108 S.Ct. 1350 (emphasis in original). In such cases, courts have concluded from the comprehensiveness of a statutory



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scheme and their interpretation of the purposes and objectives of the statute that Congress intended federal jurisdiction to be exclusive or the field to be free of any regulation whatsoever. *See, e.g., Ark. Elec. Co-op.*, 461 U.S. at 384, 103 S.Ct. 1905 (citing field preemption case for the proposition that a federal decision to forego regulation may imply an “authoritative federal determination that the area is best left unregulated;” finding no such determination); *Transcontinental Gas Pipe Line v. State Oil and Gas Bd.*, 474 U.S. 409, 422, 425, 106 S.Ct. 709, 88 L.Ed.2d 732 (1986) (finding this brand of field preemption); *Bldg. & Constr. Trades Council v. Associated Builders & Contractors*, 507 U.S. 218, 224-27, 113 S.Ct. 1190, 122 L.Ed.2d 565 (1993) (discussing two lines of such field preemption cases under the NLRA). *Cf. Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 178, 98 S.Ct. 988, 55 L.Ed.2d 179 (1978) (agency’s decision *not* to adopt a particular regulation contributed to a finding of conflict preemption where the agency took the subsequent step of adopting an alternate federal standard governing the issue with which, the Court found, the state rule would be inconsistent).

Second, other such cases appear to be simply express preemption cases—Congress and federal agencies possessing the appropriate authority certainly may announce by law or regulation a federal policy that an issue is to remain unregulated. *See, e.g., Ark. Elec. Co-op.*, 461 U.S. at 388-89, 103 S.Ct. 1905 (stating that the federal agency could have announced a policy “that the area is best left unregulated” in a “rule [ ] valid under the [Act]” but had not done so); *Wabash Valley Power Ass’n*, 903 F.2d at 453-54 (discussing *Ark. Elec.*

*Gracia v. Volvo Europa Truck*, 112 F.3d 291, 296-97 (7th Cir.1997), *cert. denied*, 522 U.S. 1050, 118 S.Ct. 697, 139 L.Ed.2d 641 (1998) (explaining that, in contrast to cases where an agency simply declined to regulate an issue, “here there is a specific federal standard ... [which] determined that this type of vehicle should be exempt from the affixing requirement ...”); *Lynnbrook Farms v. Smithkline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir.1996), *cert. denied*, 519 U.S. 867, 117 S.Ct. 178, 136 L.Ed.2d 118 (1996) (agency “declaration” of preemption issued in a formal rule); *Evans v. Bd. of County Comm’rs*, 994 F.2d 755, 758-60 (10th Cir.1993) (agency issued a “limited preemption policy” via a “Memorandum Opinion and Order” following notice and comment); *Ray*, 435 U.S. at 171-72, 98 S.Ct. 988 (stating that the federal agency could promulgate “rules” announcing that it desired *no* regulation of an issue but had not done so); *Baltimore & Ohio R.R. v. Oberly*, 837 F.2d 108, 115-16 and n. 3 (3d Cir.1988) (citing *Ray*, 435 U.S. at 172-73 & n. 23, 98 S.Ct. 988, and other cases for the same proposition).

FN7. *See, e.g., Sprietsma*, 537 U.S. at 64, 123 S.Ct. 518 (“It would have been perfectly rational for Congress not to preempt common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”); *Bates*, 544 U.S. at 449, 451, 125 S.Ct. 1788 (“[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA.... FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products’ performance in

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diverse settings ... tort suits can serve as a catalyst in this process;" concluding that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"); *Medtronic*, 518 U.S. at 487, 116 S.Ct. 2240 (plurality opinion) ("because there is no explicit private cause of action [in the federal Act] ... [a finding of preemption would mean] Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation"); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

FN8. The District Court granted the motion to dismiss relying solely on the four documents of which it took judicial notice. Accordingly, our record does not provide a full context for the Commissioner's letter. We can only say that the letter does not itself purport to be the product of an agency proceeding, and the record here does not show it to be. The record in the California litigation does reveal that the Commissioner's letter follows, and bears a striking resemblance to, a letter and memorandum that counsel at a private law firm-counsel who, according to his public law firm biography, represents the canned tuna industry in the California litigation-sent to the agency's chief counsel urging the FDA to "issue[ ] an appropriately worded letter" asserting preemption over the litigation in California and offering suggestions for the

content of such a letter. The agency had never before expressed such views. Those views apparently were formulated without the benefit of exposure to conflicting views or critiques.

FN9. Under the heading "Regulatory Action Guidance," this section offers "criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement: The composite analyzed in accordance with the applicable methods ... shows: Mercury expressed as Methyl Mercury in excess of 1 ppm (edible portion only)." *Id.*

FN10. Tri-Union's brief before us emphasizes that the FDA has also conducted an educational campaign regarding mercury in fish and that the FDA discussed mercury in its response to a citizen's petition. We have not been asked to take judicial notice of these facts, and it is not clear to us that we could do so in the context of a motion to dismiss and a complaint that does not refer to them directly or indirectly. In any event, we fail to see how an educational campaign might preempt Fellner's lawsuit, and we do not read the response to the citizen's petition to speak to a relevant issue. The citizen's petition concerned not the risks of mercury in fish specifically but rather the impact of dietary supplements of "omega-3 fatty acids" on heart disease. It discusses mercury risks only briefly, in the context of mercury's impact on the health effects of omega-3 fatty acids. The FDA merely explained that it would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited.

FN11. *See id.* at § § 341, 346, 371. The FDA has, for certain other foods, exercised this authority by affirmatively requiring particular warnings, *see, e.g.*, 21 C.F.R. §

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101.17, but it has not exercised its regulatory authority in any manner pertinent to this case.

FN12. Ultimately, misbranding liability may be imposed only by federal courts.

C.A.3 (N.J.),2008.

Fellner v. Tri-Union Seafoods, L.L.C.

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PaineWebber Inc. v. International Mobile Machines Corp.

S.D.N.Y., 1992.

Only the Westlaw citation is currently available.

United States District Court, S.D. New York.

PAINEWEBBER INC., Plaintiff,

v.

INTERNATIONAL MOBILE MACHINES CORP.,

Defendant.

No. 91 Civ. 7353(LJF).

March 30, 1992.

## ORDER AND OPINION

FREEH, District Judge.

\*1 This case involves a contract dispute between plaintiff PaineWebber Inc. ("PaineWebber") and defendant International Mobile Machines Corp. ("IMM"). PaineWebber moves for judgment on the pleadings pursuant to Fed.R.Civ.P. 12(c). For the reasons stated at oral argument and below, PaineWebber's motion is denied. Because IMM has failed to plead any factual basis for its affirmative defenses, however, those defenses are stricken, with leave to replead within twenty (20) days of the date of this Order.

## FACTS

PaineWebber filed this action to recover fees and expenses allegedly owed by IMM for financial services performed by PaineWebber in connection with IMM's sale of a license to provide cellular telephone services in Indiana. (Complaint ¶¶ 1, 7). It is undisputed that IMM sold the license at issue to Century Cellular Corp. ("Century") in a two-step transaction involving an initial loan to IMM and then the actual sale of the license. (Complaint ¶ 9; Answer ¶ 9; Motion at 2). Because the license sale required two stages (Motion at 2), however, the parties disagree as to the fee owed to PaineWebber

for the transaction. PaineWebber claims that, while it has already received \$375,000 from IMM in connection with first step of the Century license sale, it is entitled to receive approximately \$405,000 more. (Complaint ¶¶ 11-13). In response, IMM claims that the parties' written retainer agreement (the "Agreement") contemplates the payment of only one \$400,000 fee in connection with the Century transaction, and thus, that IMM owes PaineWebber only \$25,000, not \$405,000. (Answer ¶ 10). IMM further defends against any obligation to pay on the grounds that (1) PaineWebber is seeking double compensation and has failed to perform its contract obligations (First and Second Affirmative Defenses); (2) PaineWebber breached its fiduciary duties to IMM (Third Affirmative Defense); and (3) PaineWebber is estopped from asserting any claim for relief. (Fourth Affirmative Defense).

## DISCUSSION

PaineWebber moves for judgment on the pleadings, arguing that the essential elements of its claims are not disputed and that the merits of the case can be determined from the pleadings alone. (Motion at 5). In determining motions under Fed.R.Civ.P. 12(c), courts view the facts alleged in the pleadings, as well as the inferences to be drawn from those facts, in the light most favorable to the non-moving party. *Beal v. Missouri Pacific R.R. Corp.*, 61 S.Ct. 418, 421 (1941) ("Upon [a motion for judgment on the pleadings] denials and allegations of the answer which are well pleaded must be taken as true."); *Madonna v. United States*, 878 F.2d 62, 65 (2d Cir.1989) (same); 5A Wright & Miller, *Federal Practice and Procedure: Civil 2d* § 1368 at 518-19 (1990). Judgment should be entered at the pleading stage only if the moving party "clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." Wright & Miller, § 1368 at 518.

\*2 Applying this stringent standard to the facts of

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this case, it is clear that PaineWebber's motion must be denied. Even if PaineWebber is correct that the Agreement is unambiguous, and requires IMM to pay two separate fees to PaineWebber for its work in connection with the Century license transaction, IMM has raised affirmative defenses which preclude summary disposition of this case.

As discussed below, IMM's affirmative defenses are unduly vague and must be rep'd. However, in this motion, PaineWebber is seeking judgment on the pleadings, a extraordinary remedy which can be granted only in the unusual circumstance where the pleadings clearly demonstrate that one party is entitled to judgment as a matter of law. That is not the case here. Assuming, as we must, that IMM's allegations are true, PaineWebber (1) failed to perform its contract obligations; (2) breached its fiduciary duties to IMM; and (3) is estopped from asserting any claim for relief. Under those circumstances, IMM would have valid legal defenses for its failure to pay PaineWebber. At minimum, IMM is entitled to conduct discovery, in order to obtain evidence supporting its claims.<sup>FN1</sup>

Although we decline to enter judgment against IMM at this time, we agree with PaineWebber that IMM has failed to plead its affirmative defenses adequately. Under the lenient pleading requirements of the Federal Rules of Civil Procedure, a defendant need only "state in short and plain terms the ... defenses to each claim asserted ..." Fed.R.Civ.P. 8(b). But while an answer need not include a detailed statement of the applicable defenses, a defendant must do more than make conclusory allegations. See *Heller Financial, Inc. v. Midwhey Powder Co., Inc.*, 883 F.2d 1286, 1294-95 (7th Cir.1989) (striking affirmative defenses for failure to include a short and plain statement of facts and failure to allege necessary elements of the alleged claims); *Telectronics Proprietary, Ltd. v. Medtronics, Inc.*, 687 F.Supp. 832, 841 (S.D.N.Y.1988) ("the word 'estoppel' without more is not a sufficient statement of a defense").

Because IMM has failed to provide a factual basis

for any of its affirmative defenses, those defenses will be stricken. IMM may, however, replead those defenses and file an amended answer within twenty (20) days of the date of this Order. Fed.R.Civ.P. 12(f) (court may, on its "own initiative at any time," order that insufficient defenses be stricken from any pleading).

SO ORDERED.

FN1. IMM filed the affidavit of William Hilsman, as well a certain exhibits, in opposition to PaineWebber's motion. Fed.R.Civ.P. 12(c) specifically states that, in considering a motion for judgment on the pleadings, a court may consider matters outside the pleadings. If the court exercises its discretion to look beyond the pleadings, however, the court must treat the motion as one for summary judgment under Rule 56, and provide all parties with a reasonable opportunity to present all material relevant to a summary judgment motion. Given that PaineWebber was not on notice that its motion for judgment on the pleadings would be treated as one for summary judgment, and given also that little to no discovery has been conducted, it would not be appropriate to proceed with summary judgment at this time. Accordingly, the Court has not considered Mr. Hilsman's affidavit, or anything other than the pleadings in the case.

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Yash Raj Films (USA) Inc. v. Atlantic Video  
N.D.Ill.,2004.

United States District Court,N.D. Illinois, Eastern  
Division.  
YASH RAJ FILMS (USA) INC., Plaintiff,  
v.  
ATLANTIC VIDEO, et al., Defendants.  
Rajesh BANSAL, Defendant-Third Party Plaintiff,  
v.  
INDIA EMPORIUM, INC., and Sharad Shah,  
Third-Party Defendants.  
**No. 03 C 7069.**

May 28, 2004.

Daksha Amin, Law Offices of Daksha Amin,  
Chicago, IL, William Michael Poppe, Megha  
Bhouraskar, Poppe & Bhouraskar, LLP, New York,  
NY, for Plaintiff.

Gerald L. Berlin, Law Offices of Gerald L. Berlin,  
Chicago, IL, for Defendants.

John William Moore, John C. Spieske, Moore &  
Spieske, P.C., Chicago, IL, for Defendants and  
Third-Party Plaintiff.

Sharad Shah, Diamond Bar, CA, pro se.

MEMORANDUM OPINION GRANTING IN  
PART AND DENYING IN PART DEFENDANT-  
THIRD PARTY PLAINTIFF'S MOTION TO  
STRIKE

FILIP, J.

\*1 Before the Court is Defendant-Third Party Plaintiff Rajesh Bansal's ("Bansal") motion to strike all of Third-Party Defendant Sharad Shah's ("Shah") affirmative defenses. Bansal variously alleges that the affirmative defenses do not meet the pleading requirements of Fed.R.Civ.P. 8(a) ("Rule 8(a)"), that they are conclusory allegations, and that they are not affirmative defenses under Fed.R.Civ.P. 8(c) ("Rule 8(c)").<sup>FN1</sup> As explained below, the Court grants the motion to strike affirm-

ative defenses one through six, eight through eleven, and thirteen. The Court denies the motion to strike affirmative defenses seven and twelve.

FN1. It appears that Bansal's motion to strike may not have been timely under Fed.R.Civ.P. 12(f) ("Rule 12(f)"). However, "Rule 12(f) 'gives unrestricted authority to the district court to strike insufficient defenses.'" *Go-Tane Serv. Stations, Inc. v. Ashland Oil, Inc.*, 508 F.Supp. 200, 201-02 (N.D.Ill.1981) (quoting *United States v. 416.81 Acres of Land*, 514 F.2d 627, 630 n. 3 (7th Cir.1975)).

## BACKGROUND

Plaintiff, Yash Raj Films (USA), Inc., alleges in its first amended complaint that it is the owner of the copyrights and/or exclusive license rights of certain Indian films.<sup>FN2</sup>(D.E.9, ¶ 49.) Plaintiff alleges that Defendant-Third Party Plaintiff, Bansal, has made, copied, purchased, sold, rented and/or distributed unauthorized "pirate" copies of Plaintiff's films, in some cases using Plaintiff's name or logo on the package. (*Id.* ¶ 65.)The complaint further alleges that Bansal has not obtained any assignment, license, authorization, permission or consent to any rights to Plaintiff's films.(*Id.* ¶ 71.)

FN2. Yash Raj filed a second amended complaint after the motion addressed in this decision; however, the amended complaint does not impact the analysis of the Court.

Bansal alleges in the Third Party Complaint that Shah is in the business of selling DVDs of Indian films and music and that Bansal has purchased DVDs of Indian films and music from Shah. (D.E.17, ¶ 8,9.) Bansal purchased from Shah items which Plaintiff, Yash Raj Films, alleges infringe its copyrights and trademarks. (*Id.* ¶ 9). Bansal alleges that every sale by Shah contained an implied war-

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ranty of non-infringement under section 312 of article two of the Uniform Commercial Code ("U.C.C."), which is incorporated into Illinois law as 810 ILCS 5/2-312. (*Id.* ¶ 10.) In addition, Bansal alleges that, upon specific inquiry, Shah represented that the goods sold by Shah were non-infringing. (*Id.* ¶ 11.) Bansal contends that this constituted an express warranty by Shah under section 313 of article two of the U.C.C., which is incorporated into Illinois law as 810 ILCS 5/2-313. (*Id.*) Bansal further alleges that pursuant to sections 312 and 313 of article two of the U.C.C., Shah has a duty to defend and indemnify Bansal against some or all of the claims of Plaintiff. (*Id.* ¶ 12.)

Shah generally denies the allegations of the Third-Party Complaint and sets forth thirteen affirmative defenses. (D.E.19.) Shah asserts failure to state a cause of action, declaratory relief, ratification, waiver, estoppel, laches, failure to mitigate damages, unclean hands, statute of limitations, intentional conduct, apportionment of fault, set off, and Fed. R.Civ. P. 11 ("Rule 11") as affirmative defenses, respectively. (*Id.* at 3-7.)

#### DISCUSSION

Bansal objects to affirmative defenses one and three through twelve (failure to state a claim, ratification, waiver, estoppel, laches, failure to mitigate damages, unclean hands, statute of limitations, intentional conduct, apportionment of fault, and set off) based on a contention that they are conclusory allegations that fail to provide fair notice of the defense. (D.E.22, ¶ 8-43.) Bansal objects to affirmative defenses two, declaratory relief, and thirteen, Rule 11, based on the contention that they are not matters which constitute an avoidance or affirmative defense as set forth in Rule 8(c). (*Id.* ¶ 11, 45.) Bansal further objects to affirmative defense thirteen (generically asserting an undefined Fed.R.Civ.P. 11 violation), contending that it does not comply with Rule 11(c)(1)(A) in that it is not presented in a separate motion and does not describe the specific conduct alleged to violate Rule

11(b). (*Id.* ¶ 46.) The Court agrees that affirmative defenses one through six, eight through eleven, and thirteen are inadequate, as further explained below.

\*2 The purpose of Rule 8(c) is to give the opposing party notice of the affirmative defense and a chance to rebut it. *See Servpro Indus. Inc. v. Schmidt*, 905 F.Supp. 475, 483 (N.D.Ill.1995) (collecting authorities). Rule 8(c) provides that a party must set forth affirmative defenses in a responsive pleading. These pleadings are subject to all pleading requirements of the Federal Rules of Civil Procedure. *See Heller Fin., Inc. v. Midwhey Powder Co.*, 883 F.2d 1286, 1294 (7th Cir.1989). The Court may strike from any pleading any insufficient defense. *See Fed.R.Civ.P. 12(f)*. Affirmative defenses must set forth a "short and plain statement" of the basis for the defense. Fed.R.Civ.P. 8(a); *accord Heller*, 883 F.2d at 1294. However, an allegation must include either direct or inferential allegations respecting all material elements of the defense asserted. *See, e.g., Renalds v. S.R.G. Rest. Group*, 119 F.Supp.2d 800, 802 (N.D.Ill.2000) (collecting authorities). Simply naming a legal theory without indicating how it is connected to the case at hand is not sufficient to withstand a motion to strike. *Id.* at 803.

Courts generally disfavor motions to strike affirmative defenses because they potentially serve only to cause delay. *See Heller*, 883 F.2d at 1294. However, the courts should strike affirmative defenses where they are mistitled, or redundant-*see, e.g., Renalds*, 119 F.Supp.2d at 802-or where they create unnecessary clutter. *See, e.g., Heller*, 883 F.2d at 1294. This district has followed a three-part test in examining affirmative defenses subject to a motion to strike, requiring that: (1) the matter must be properly pleaded as an affirmative defense; (2) the matter must be adequately pleaded under the requirements of Federal Rules of Civil Procedure 8 and 9; and (3) the matter must withstand a Rule 12(b)(6) challenge. *See, e.g., Renalds*, 119 F.Supp.2d at 802-3 (collecting authorities).

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#### A. First and Ninth Affirmative Defenses

Affirmative defense one, failure to state a claim, requires a short and plain statement of the basis for the defense as is set forth in Rule 8(a). Defenses which are bare bones legal conclusions are not sufficient to survive a motion to strike. *See Heller*, 883 F.2d at 1295; *Builder's Bank v. First Bank & Trust Co. of Ill.*, No.03-4959, 2004 WL 626827, at \*3 (N.D.Ill. Mar.25, 2004) (collecting cases). Shah's first affirmative defense is a boilerplate legal conclusion and does not specify reasons why Bansal failed to state a claim. Similarly, affirmative defense nine, relating generically to statute of limitations issues, fails to state the statute of limitation period relied on or any other information regarding how the statute of limitations bars the claim. It is not even clear what state's law Shah purports to invoke when he offers incomplete citations to the "Code of Civil Procedure" in Shah's otherwise conclusory averment. These two defenses are impermissible conclusory statements. The Court grants the motion to strike affirmative defenses one and nine without prejudice.

#### B. Third through Sixth and Eighth Affirmative Defenses

\*3 Affirmative defenses three through six and eight, (ratification, waiver, estoppel, laches, and unclean hands, respectively) are equitable defenses that must be pled with the specific elements required to establish the defense. *See, e.g., Fluor Corp. v. Ill. Power Co.* 326 F.2d 374, 377-78 (7th Cir.1964); *Bobbitt v. Victorian House, Inc.*, 532 F.Supp. 734, 738-39 (N.D.Ill.1982). These defenses require at least some direct or inferential allegations as to each element of the defense asserted. *See Builder's Bank*, 2004 WL 626827, at \*5. Courts have set forth specific pleading standards for the defenses of waiver, estoppel, and laches and have "consistently struck these defenses where they are insufficiently pled." *Id.*, at \*6. In addition, stringing together a list of legal defenses is not sufficient to satisfy Rule 8(a). *Id.* Shah has not provided the suf-

ficient elements or allegations to establish these affirmative defenses. The Court grants the motion to strike affirmative defenses three through six and eight without prejudice.

#### C. Tenth and Eleventh Affirmative Defenses

Affirmative defense ten, intentional conduct, and eleven, apportionment of fault, in addition to being legal conclusions, are defenses which need not be pled to be proved. Under federal law, affirmative defenses generally admit the matters in a complaint but nevertheless assert facts that would defeat recovery. *See, e.g., Bobbitt*, 532 F.Supp. at 736. Affirmative defense ten, intentional conduct, operates to reduce liability on a comparative fault basis or operates as a denial of liability altogether, and as such, does not qualify as an affirmative defense. *See Fed. Deposit Ins. Corp. v. Haines*, 3 F.Supp.2d 155, 166 (D.Conn.1997). Causation is necessarily an element of the Plaintiff's case in chief. *Id.* Likewise, affirmative defense eleven, apportionment of fault, is a denial and claim that others are responsible. Matters that clearly are not affirmative defenses should be stricken. *See, e.g., Bobbitt*, 532 F.Supp. at 737. If the matter is put into issue by a denial, there is no need to insert a putative affirmative defense. *Id.* The Court grants the motion to strike affirmative defenses ten and eleven with prejudice.

#### D. Second and Thirteenth Affirmative Defenses

Affirmative defense two, declaratory relief, and thirteen, Rule 11, do not qualify as affirmative defenses. Affirmative defense two is a denial of responsibility and request for relief without details or allegations explaining why declaratory relief for Shah is warranted. A declaratory request for declaratory relief is not a matter which constitutes an avoidance or affirmative defense as set forth by Rule 8(c). This affirmative defense is both unnecessary and inappropriate because the assertion is already put into issue by the denial in Shah's an-

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swer. *See, e.g., Renalds*, 119 F.Supp.2d. at 804 (collecting cases). Affirmative defense thirteen, alleging an unspecified violation of Rule 11, is improper and does not qualify as an affirmative defense. Rule 11 requires that this allegation be brought as a separate motion at the appropriate time. *See Fed.R.Civ.P. 11(1)(A)*. The Court grants the motion to strike affirmative defenses two and thirteen with prejudice.

So Ordered.

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#### E. Seventh and Twelfth Affirmative Defenses

\*4 Affirmative defense seven, failure to mitigate damages, may be a partial defense pled affirmatively. *See generally* 5 Charles Alan Wright and Arthur R. Miller, Federal Practice and Procedure § 1273 (2d ed.1990). The pleading sufficiently informs Bansal of the issue raised and it would be unreasonable to expect Shah to have detailed information about mitigation at this early stage of litigation. *See Cohen v. Taco Bell*, No. 92-5852, 1995 WL 247996, at \*5 (N.D.Ill. Apr.24, 1995). Shah may be able to prove facts to support this defense. Likewise, affirmative defense twelve, set off, withstands the motion to strike. Shah may be able to prove facts to support this defense but, at this point in the litigation, Shah does not have access to information that would enable Shah to state such a defense with more particularity. In addition, set off raises an issue not raised in Shah's answer and places Bansal on notice of the potential defense. The Court denies the motion to strike affirmative defenses seven and twelve.

#### CONCLUSION

For the foregoing reasons, the motion to strike affirmative defenses one through six, eight through eleven and thirteen is granted. Affirmative defenses one, three through six, and eight through nine are stricken without prejudice. Affirmative defenses two, ten, eleven, and thirteen are stricken with prejudice. The motion to strike affirmative defenses seven and twelve is denied.